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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,814	05/11/2005	Rainer Hipfel	P67564US1	4911
136 7590 03/09/2009 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			EXAMINER ULM, JOHN D	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 03/09/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,814

Applicant(s)

HIPFEL ET AL.

Examiner

John D. Ulm

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5-32 is/are pending in the application.
- 4a) Of the above claim(s) 11-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date 9/16/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1) Claims 1, 2 and 5 to 32 are pending in the instant application. Claims 1, 2, 6 to 8, 11 to 25 and 30 to 32 have been amended and claims 3 and 4 have been canceled as requested by Applicant in the correspondence filed 11 December of 2008.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

4) Claims 11 to 32 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08 February of 2008.

Claim Rejections - 35 USC § 112

5) Claims 1, 2 and 5 to 10 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record as applied to claims 1 to 10 in section 6 of the office action mailed 26 May of 2006.

These claims are directed to a method of diagnosing or monitoring the progression of a neurodegenerative disease in a subject by measuring the expression

level of a protein identified in the specification as "SCN2A" in a sample from that subject and comparing that expression level to a reference value. The claims are not enabled because the specification fails to disclose an established nexus between the expression level of "SCN2A" and the presence or progression of neurodegenerative diseases in general. Further, the specification fails to show any difference between the expression level of "SCN2A" in living subjects suffering from any particular neurodegenerative disease or disorder and the expression level of that protein in living subjects that are free of that disease or disorder. And finally, whereas there is no "Table 1" or "Table 2" in the instant application, the value range for the expression level of "SCN2A" in post mortem brain samples from Alzheimer's diseased patients and healthy individuals, as given on pages 33 and 34 of the instant specification overlap, indicating that the level of expression of "SCN2A" in a post mortem brain may, or may not be indicative of the presence of Alzheimer's disease in the corpse from which it was derived. In summary, the instant claims are not enabled because the instant specification provides no evidence that the expression level of "SCN2A", as measured in sample and, in particular, cerebrospinal fluid, differs between healthy living individuals in general and in living individuals suffering from a neurodegenerative disease and, in particular, Alzheimer's diseased.

Applicant's argument that the claims are now limited to Alzheimer's disease is not supported by the claims of record and, even if it was, such a limitation would not avoid the above rejection.

Claim Rejections - 35 USC § 102

6) Claims 1, 5 and 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by the Planells-Cases et al. publication (Biophys. J. 78:2878-2891, 2000), cited by Applicant) for those reasons of record in section 8 of the office action mailed 26 May of 2006. As stated therein, Figure 2A on page 2882 of the Planells-Cases et al. publication anticipates the instant claims because it disclose a method of diagnosing a disease that results in massive apoptosis (see abstract) by measuring and comparing the expression level of SCNA2 mRNA from a subject in which the SCNA2 gene that has been disrupted a control subject not suffering from the genetic disruption.

As indicated above, Applicant's traversal of this rejection on the premise that the claims are now limited to Alzheimer's disease is not supported by the claims of record.

Claim Rejections - 35 USC § 103

7) Claims 2 and 8 to 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Planells-Cases et al. publication (Biophys. J. 78:2878-2891, 2000), cited by Applicant) for those reasons of record as applied to claims 2, 3 and 8 to 10 in section 10 of the office action mailed 26 May of 2006.

Response to Arguments

8) Applicant's arguments filed 11 December of 2008 have been fully considered but they are not persuasive.

Conclusion

9) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/
Primary Examiner, Art Unit 1649